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ATTORNEY DOCKET NO.: 05552.1442

**Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231**

New U.S. Patent Application

Title: CLOSURE APPLIANCE FOR REAGENT CONTAINERS

Inventors: Ralf OTTO, Hugo WILMES, and Hans Dieter SÄNGER

Sir:

We enclose the following papers for filing in the United States Patent and Trademark Office in connection with the above patent application.

1. A check for \$730 representing a \$690 filing fee and \$40 for recording the Assignment.
2. Application - 11 pages, including 2 independent claims and 7 claims total.
3. Drawings - 14 sheets of drawings containing 27 figures.
4. Declaration and Power of Attorney.
5. Recordation Form Cover Sheet and Assignment to Dade Behring Marburg GmbH.
6. Certified copy of German Application No. 199 17 646.9, filed April 19, 1999.
7. Information Disclosure Statement and Information Disclosure Citation, PTO 1449 with 3 documents attached.

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Assistant Commissioner for Patents
April 18, 2000
Page 2

8. Preliminary Amendment
9. Request for Approval of Drawing Change and amended Figures 13 and 14.

Applicants claim the right to priority based on German Application No. 199 17 646.9, filed April 19, 1999.

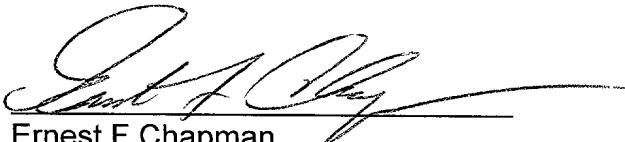
Please accord this application a serial number and filing date and record and return the Assignment to the undersigned.

The Commissioner is hereby authorized to charge any additional filing fees due and any other fees due under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By:


Ernest F Chapman
Reg. No. 25,961

EFC/dvz
Enclosures

PATENT
Attorney Docket No. 5552.1442-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Ralf OTTO et al.)
Serial No.: Not Assigned) Group Art Unit: Unknown
Filed: April 18, 2000) Examiner: Unknown
For: CLOSURE APPLIANCE FOR)
REAGENT CONTAINERS)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

IN THE SPECIFICATION:

Please amend the specification with reference to its numbered lines as follows:

Page 1, lines 1-3, delete in their entirety;

before line 6, insert in the center of the page -- BACKGROUND OF THE
INVENTION -- and directly below, at the left-hand margin, insert -- Field of the
Invention --; and

line 12, insert at the left-hand margin -- Description of the Related Art --.

Page 2, line 24, insert in the center of the page -- SUMMARY OF THE
INVENTION --.

Page 3, line 22, change "shows" to --is an isometric view of a first embodiment
of--;

line 24, change "shows" to --is an isometric view of-- and after "appliance" insert --of Fig. 1--;

line 26, insert --and-- after "position,";

line 28, change "shows" to --is an isometric view of the transfer appliance of Fig. 1 with--;

line 29, insert --and-- after "position,";

line 31, change "shows" to --is an isometric view of the transfer appliance of Fig. 1 with -- and after "position," insert --and--;

line 33, change "shows" to --is an isometric view of the transfer appliance of Fig. 1 with-- and after "position," insert --and--;

line 35, change "shows" to --is an isometric view of the transfer appliance of Fig. 1 with--;

line 36, after "position," insert --and--; and

line 38, change "shows" to --is an isometric view of the transfer appliance of Fig. 1 with--.

Page 4, line 2, after "closed," insert --and--;

line 3, change "shows" to --is an isometric view of-- and after "appliance" insert --of Fig. 1--;

line 7, change "shows" to --is a partial isometric view of a second embodiment of a transfer appliance according to the present invention,--

line 10, after "position," insert --and--;

line 11, change "shows" to --is a partial isometric view of the device of Fig. 9 with--;

line 13, after "position," insert --and--;

line 18, change "Fig. 12 shows" to --Figs. 12a-12f are various isometric views of--;

line 21, change "Fig. 13 shows" to --Fig. 13a is a top view of an open stopper lid of a reagent container according to the present invention; Fig. 13b is a cross-sectional view of the reagent container of Fig. 13a taken along line A-A; and Figs. 13c-13e are various isometric views of--;

line 23, change "Fig. 14 shows" to --Fig. 14a is a top view of a closed stopper lid of a reagent container according to the present invention; Fig. 14b is a cross-sectional view of the reagent container of Fig. 14a taken along line A-A; and Figs. 14c-14e are various isometric views of--;

line 25, insert in the center of the page -- DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS --;

line 26, insert --transfer-- before "appliance,"; and

line 27, change "Figures" to --Figs.--.

Page 5, line 1, insert --horizontal-- before "movement";

line 2, after "container" insert --on the guide (17)-- and delete "via the catch";

line 3, delete "(15),";

line 4, after "opened" insert --via the catch (15)--;

line 26, change "a further" to --an alternative--;

line 27, before "appliance" insert --transfer--; and

line 28, after "Further" insert --alternative-- and delete "patent".

IN THE CLAIMS:

Please cancel claims 1-6 and add new claims 7-13 as follows:

~~--7.~~ An appliance for opening and closing reagent container stoppers in partially or fully automatic analysis apparatus, comprising:

 a plunger for engaging and releasing a catch on a reagent container stopper to be opened, the plunger moveable between an at rest position and a working position;

 an automatic conveyor for moving the reagent containers relative to the plunger; and

 structure for translating movement of a pipetting-needle carrier to the plunger to cause movement of the plunger.

8. The appliance of claim 1, wherein the translated movement of the pipetting-needle carrier is upward movement.

9. The appliance of claim 2, wherein the structure for translating movement includes two rocker arms and a stop rod.

10. The appliance of claim 2, further comprising a traction drive for moving the pipetting-needle carrier.

11. The appliance of claim 10, wherein the structure for translating movement includes a thrust plate and a catch member.

~~12.~~ A method for opening and closing a reagent container stopper in partially or fully automatic analysis apparatus, comprising:

 moving a plunger from an at-rest position to a working position;

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engaging a catch on a reagent container stopper with the plunger;
moving the reagent container stopper with the catch relative to the plunger
to at least partially open the stopper to enable liquid transfer via a pipette; and
closing the reagent container stopper.

13. The method of claim 12, wherein the moving includes translating motion
of a pipetting needle assembly to move the plunger.--

REMARKS

The specification has been amended to place it in proper U.S. format, and to
correct grammatical and idiomatic errors. Claims 1-6 have been canceled and rewritten
as new claims 7-13 to provide claims in proper U.S. format.

If there is any fee due in connection with the filing of this amendment, please
charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Elizabeth M. Burke
Elizabeth M. Burke
Reg. No. 38,758

Dated: April 18, 2000

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Closure appliance for reagent containers

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The invention relates to an appliance for opening and closing a reagent-container stopper in a partially or fully automatic analysis apparatus, and to the method, which is applied by means of this appliance, for 10 opening and closing a reagent-container stopper in a partially or fully automatic analysis appliance.

Partially or fully automatic analysis apparatus are in widespread use in medical diagnostics, but also in 15 other fields, for example in analytics. These apparatus essentially comprise three components, a reagent part, a sample part and an analysis part. A certain number of reagents are stored in reagent containers in the reagent part. The reagents must as far as possible be 20 hermetically sealed, in order to prevent contamination and evaporation. A certain number of samples are stored in the sample part. The samples too should also be as far as possible sealed in an airtight manner, possibly for safety reasons, e.g. contamination and potential 25 risk of infection. Furthermore, it is advantageous for the individual compartments, i.e., for example, the entire reagent part or sample part, to be protected against contamination by means of a cover. The necessary transfer of liquids between the individual 30 parts is generally carried out by means of transfer pipettes which, depending on the particular requirements, can move in the X-, Z- and/or Y-direction and/or in the phi-direction (angular rotation). This movement is often driven by stepper motors, in which 35 case one motor is provided for each direction of movement. Owing to the different filling volumes and the different shapes of the reagent and/or sample containers - in the following text reagent and sample containers are referred to generally as reagent 40 containers - the maximum movement in the Z-direction is

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under certain circumstances extremely great; it may be, for example, from 10 to 200 mm.

These requirements have led to various proposed solutions for the design of reagent-container stoppers.

5 In this context, it is necessary to distinguish between two groups of solutions, on the one hand "passive" systems, in which the reagent-container stopper is designed in such a way that reclosure is to be ensured by the elasticity of the stopper material, as proposed,

10 for example, in EP 0,509,281, and on the other hand "active" systems, in which opening and closing have to take place actively, as described, for example, in EP 0,543,638. However, this document does not provide any description of a possible solution to the question of

15 how the above-described stopper can be opened or closed. The earlier application DE 197 46 169 describes an active reagent-container stopper which is moved by means of a plunger, but this document does not describe any possible way of executing this movement. In

20 practice, the compartment cover presents additional problems. For the reasons listed above, the reagent containers should also only be open at the moment at which the removal is taking place.

25 The present invention is therefore based on the object of finding the most simple possible method for actuating an active reagent-container stopper. At the same time, the method is to be arranged in such a way that the appliances which are required for the method can, if appropriate, even be retrofitted to already

30 existing apparatus.

35 This object is achieved by means of an appliance which essentially makes use of the existing vertical movement sequences of the pipette-needle carrier (4), without in doing so impairing the freedom of movement of the pipetting needle.

Advantageously, the upward movement of the pipette carrier is utilized, in that the upward movement of the pipette carrier is transmitted to the plunger (11) by means of a means which is known per se to the person skilled in the art and reverses the direction of movement, with the result that the plunger is moved downward out of the at-rest position into the working position. The utilization of the upward movement allows the plunger travel to be made independent of the immersion depth of the pipetting needle.

It is known to the person skilled in the art that, for example, forces can be transmitted in a wide variety of ways - e.g. by means of a suitable lever mechanism, a traction drive, a hydraulic appliance or a Bowden cable - so that the embodiments described below are simply intended to explain the invention, without limiting it in any way.

20 Brief description of the figures:

Fig. 1 shows the transfer appliance with the rocker arm mechanism in the displacement position;

25 Fig. 2 shows the transfer appliance in the transfer position, the pipetting-needle carrier (4) in the displacement position, the plunger (11) in the at-rest position;

30 Fig. 3 shows the pipetting-needle carrier (4) in the upper position, the plunger (11) in the working position;

Fig. 4 shows the plunger (11) in the working position, the reagent-container carrier (16) in motion;

35 Fig. 5 shows the reagent-container stopper (13) open, the pipetting needle in the pipetting position;

Fig. 6 shows the pipetting-needle carrier (4) in the upper position, the plunger (11) in the working position;

Fig. 7 shows the pipetting-needle carrier (4) in the upper position, the plunger (11) in the working

position, the reagent-container stopper (13) closed, the catch (15) elastically deflected;

5 Fig. 8 shows the transfer appliance pivoting into the displacement position, the pipetting-needle carrier (4) in the displacement position, the plunger (11) in the at-rest position;

10 Fig. 9 shows the transfer appliance with the toothed belt (26) in the transfer position, the pipetting-needle carrier (4) in the upper position, the ram (11) in the working position;

15 Fig. 10 shows the transfer appliance in the displacement position, the pipetting-needle carrier in the displacement position, the thrust plate (27) in the at-rest position;

20 Fig. 11 shows the reagent-container stopper (13) open, the pipetting needle in the pipetting position, the plunger (11) in the at-rest position;

25 Fig. 12 shows the reagent-container stopper (13), dismantled into reagent-container stopper lid (14) and reagent-container stopper body (19);

Fig. 13 shows the reagent container (12) with reagent-container stopper (13) open;

Fig. 14 shows the reagent container (12) with reagent-container stopper (13) closed.

25

One embodiment of the appliance according to the invention is described by way of example in Figures 1 to 8:

30 1) the pipetting needle (3), which is suspended from a bearing arm (2), is moved into a position above the opening in the reagent container (12), which at this time is still closed;

35 2) the pipetting-needle carrier (4) is moved upward out of the displacement position, and in the process the movement is transmitted, via the catch (7), the rocker arm I (8), the stop rod (9) and the rocker arm II (10), to the plunger (11), which as a result is moved out of the at-rest position into the working position;

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3) as a result of the movement of the reagent container relative to the plunger, via the catch (15), the lid of the reagent-container stopper is opened and the reagent container is moved into the removal position;

5 4) as a result of the downward movement of the pipetting-needle carrier (4), in the reverse of the movement from step 2, plunger (11) is moved back into the at-rest position by means of spring

10 10 force;

15 5) the pipetting needle (3) removes the transfer material;

6) the subsequent upward movement of the pipetting-needle carrier (4) results in the movement sequence from step 2 being repeated, with the result that plunger (11) is moved out of the at-rest position into the working position,

15 7) as a result of suitable movement of the reagent container relative to the plunger, the lid of the reagent-container stopper is closed by means of the catch (15), and the reagent container is moved into an at-rest position;

20 8) the transfer device is now ready for the next transfer operation.

25

Figures 9 and 10 show a further advantageous configuration of the appliance according to the invention. In a similar manner to the exemplary embodiment described above, in this embodiment the movement of the toothed belt (26), which moves the pipetting-needle carrier (4), is utilized in order to move the plunger (11).

Further embodiments are described in the patent claims.

35 The pipetting-needle carrier (4) is moved upward out of the displacement position, and in the process the movement is transmitted, via the catch (7) and a thrust plate (27), to the plunger (11), which consequently is

moved out of the at-rest position into the working position.

The use of a thrust plate allows even a plunger which

5 is at a three-dimensional distance from the removal position to be moved, so that consequently there is a greater degree of freedom in the design of the actual embodiment of the invention.

10 The reagent-container stoppers may be designed in many ways. For example, EP 0,543,638 describes reagent-container stoppers which are opened by a rocker mechanism which can be moved by the plunger (10) according to the invention. DE 197 46 169 describes

15 reagent-container stoppers which are essentially distinguished by the fact that the lids can be pivoted upward and sideways by means of an inclined, bistable hinge.

20 It is advantageously also possible to use, for example, the two-piece reagent-container stoppers illustrated in Figures 9 to 11. The reagent-container stopper (13) comprises a reagent-container stopper lid (14) and the reagent-container stopper body (19). The two parts are

25 connected to one another by means of a coupling pin (20). The material used is advantageously a partially elastic plastics material, such as for example polypropylene for the reagent-container stopper lid (14) and polyethylene for the reagent-container stopper body (19). The substantially horizontal movement of the lid in a single plane allows this reagent-container stopper to be of very simple structure. The opening (21) is advantageously sealed by the lid (22) by

30 designing the seal (21/22) in the shape of a segment of a sphere.

35

A particularly well-sealed closure of the lid can be achieved if a lug (23) is arranged on the lid, which

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lug runs in a guide (24) and thus ensures a pressure-loaded seal between the lid and the opening (21).

5 The advantageous design of the seal in the shape of a segment of a sphere makes it possible to dispense with a special sealing insert.

The reliability of the analysis results can be visually improved still further by means of the reagent-container stopper according to the invention by providing the reagents which are required for a specific detection with reagent-container stoppers which are of the same color.

15 Figs. 12 and 13 show the reagent container with the
reagent-container stopper according to the invention in
the open and closed positions, respectively. While the
reagent-container stopper may be made from one or more
different plastics materials, the reagent container
20 itself is preferably made from a transparent plastics
material or glass. It is particularly advantageous for
it to be possible for reagent vessels of different
designs to be closed using the same reagent-container
stopper according to the invention and to be inserted
25 into an automatic analyzer in this way.

The reagent-container stopper is opened and closed by the plunger (11), which moves relative to the reagent container, engages on a catch (15) arranged on the stopper which is to be opened and opens the lid at a predetermined position. The plunger (11), which causes the reagent-container stopper to open and close, can be actuated by the appliance according to the invention. The catch (15) is preferably designed in such a way that, in the limit position, it can be elastically deflected so far by the plunger that the plunger (11) can be moved beyond the limit position on the reagent container.

List of reference numerals:

20554550
100-1000

- (1) rotatable support column
- (2) bearing arm
- 5 (3) pipetting needle
- (4) pipetting-needle carrier, vertically movable
- (5) vertical guide for the pipetting-needle carrier
- (4)
- (6) abutment
- 10 (7) catch
- (8) rocker arm I
- (9) stop rod
- (10) rocker arm II
- (11) plunger
- 15 (12) reagent container
- (13) reagent-container stopper
- (14) reagent-container stopper lid
- (15) partially elastic catch
- (16) reagent-container carrier, horizontally movable
- 20 (17) guide for the reagent-container carrier
- (18) restoring spring
- (19) reagent-container stopper body
- (20) coupling pin
- (21) bottom shell of the seal, in the shape of a
- 25 segment of a sphere
- (22) top shell of the seal, in the shape of a segment
- of a sphere
- (23) guide lug
- (24) guide
- 30 (25) bar code
- (26) toothed belt
- (27) thrust plate
- (28) thrust-plate abutment

Patent claims:

5

1. Appliance for opening and closing a reagent-container stopper in a partially or fully automatic analysis apparatus, in which

10

a) a plunger (11) is moved sufficiently far out of an at-rest position into a working position for it to engage on a catch (15) arranged on a reagent-container stopper,

15

b) the automatic onward conveying of the reagent container opens the stopper at least sufficiently far for it to be possible for liquid transfer to be carried out by means of a transfer pipette, and

20

c) following the liquid transfer, the reagent-container stopper is closed again,

25

wherein the plunger (11) is moved out of the at-rest position into the working position by means of a suitable appliance as a result of a movement of the pipetting-needle carrier (4) or as a result of a movement of the appliance which causes the movement of the pipetting-needle carrier.

30

2. The appliance as claimed in claim 1, in which the movement of the pipetting-needle carrier (4) is an upward movement.

35

3. The appliance as claimed in claim 2, in which the movement of the pipetting-needle carrier (4) is transmitted by a combination of the rocker arms (8) and (19) and the stop rod (9).

4. The appliance as claimed in claim 2, in which the appliance which causes the movement of the pipetting-needle carrier and of the catch (7) is a traction drive.

5

5. The appliance as claimed in claim 4, in which the appliance for transmitting the movement comprises the catch (7) and the thrust plate (27).

10 6. A method for opening and closing a reagent-container stopper in a partially or fully automatic analysis apparatus, in which

15 a) a plunger (10) is moved sufficiently far vertically downward out of an at-rest position into a working position for it to engage on a catch (4) arranged on a reagent-container stopper,

20 b) the automatic onward conveying of the reagent container opens the stopper at least sufficiently far for liquid transfer to be carried out by means of a transfer pipette, and

25 c) after the liquid transfer, the reagent-container stopper is closed again,

30 wherein the plunger (11) is moved out of the at-rest position into the working position by means of a suitable appliance as a result of a movement of the pipetting-needle carrier (4) or as a result of a movement of the appliance which causes the movement of the pipetting-needle carrier.

Abstract

5

Closure appliance for reagent containers

The invention relates to an appliance for opening and closing a reagent-container stopper in a partially or fully automatic analysis apparatus, and to the method, which is applied by means of this appliance, for opening and closing a reagent-container stopper in a partially or fully automatic analysis appliance.

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Fig. 1

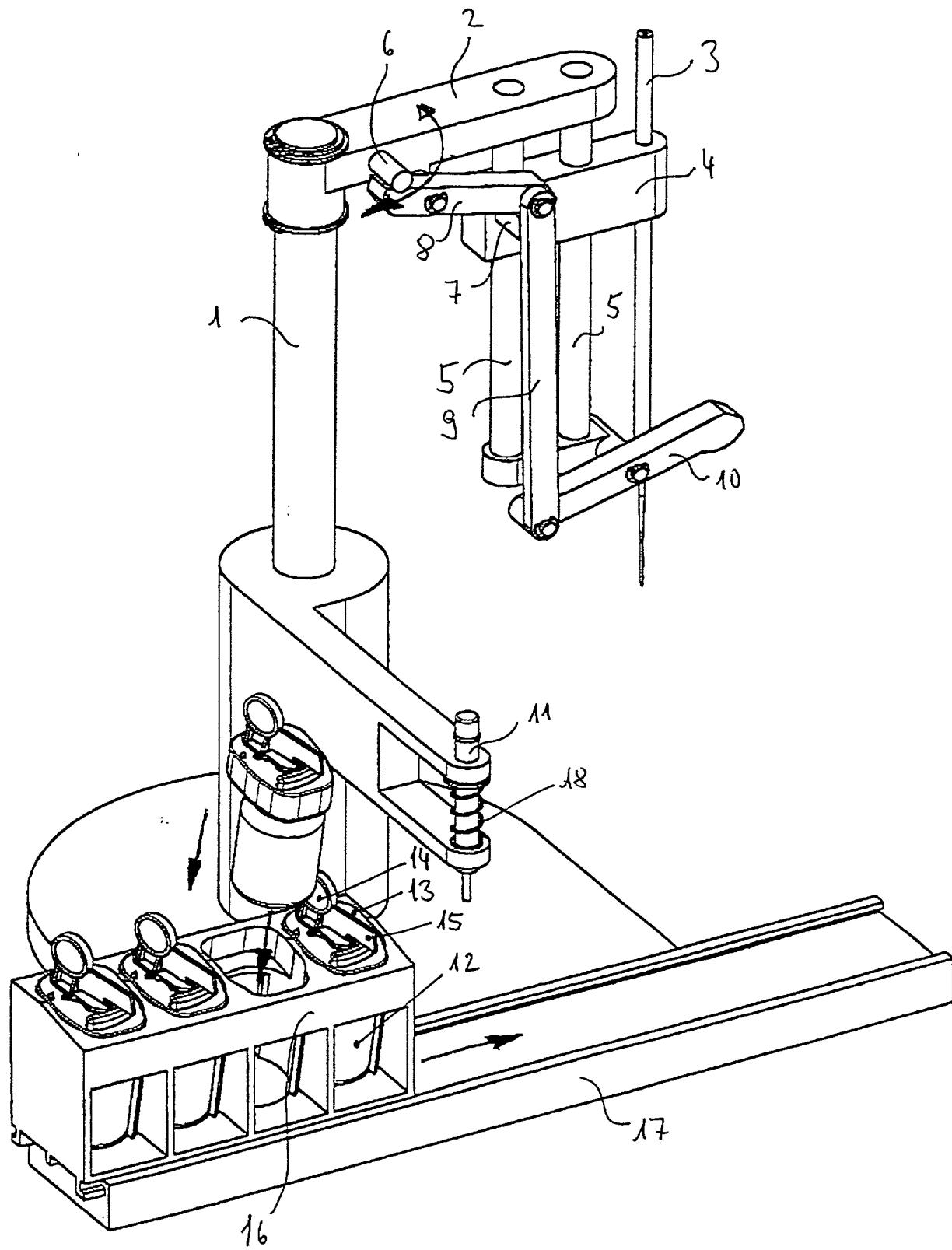


Fig. 2

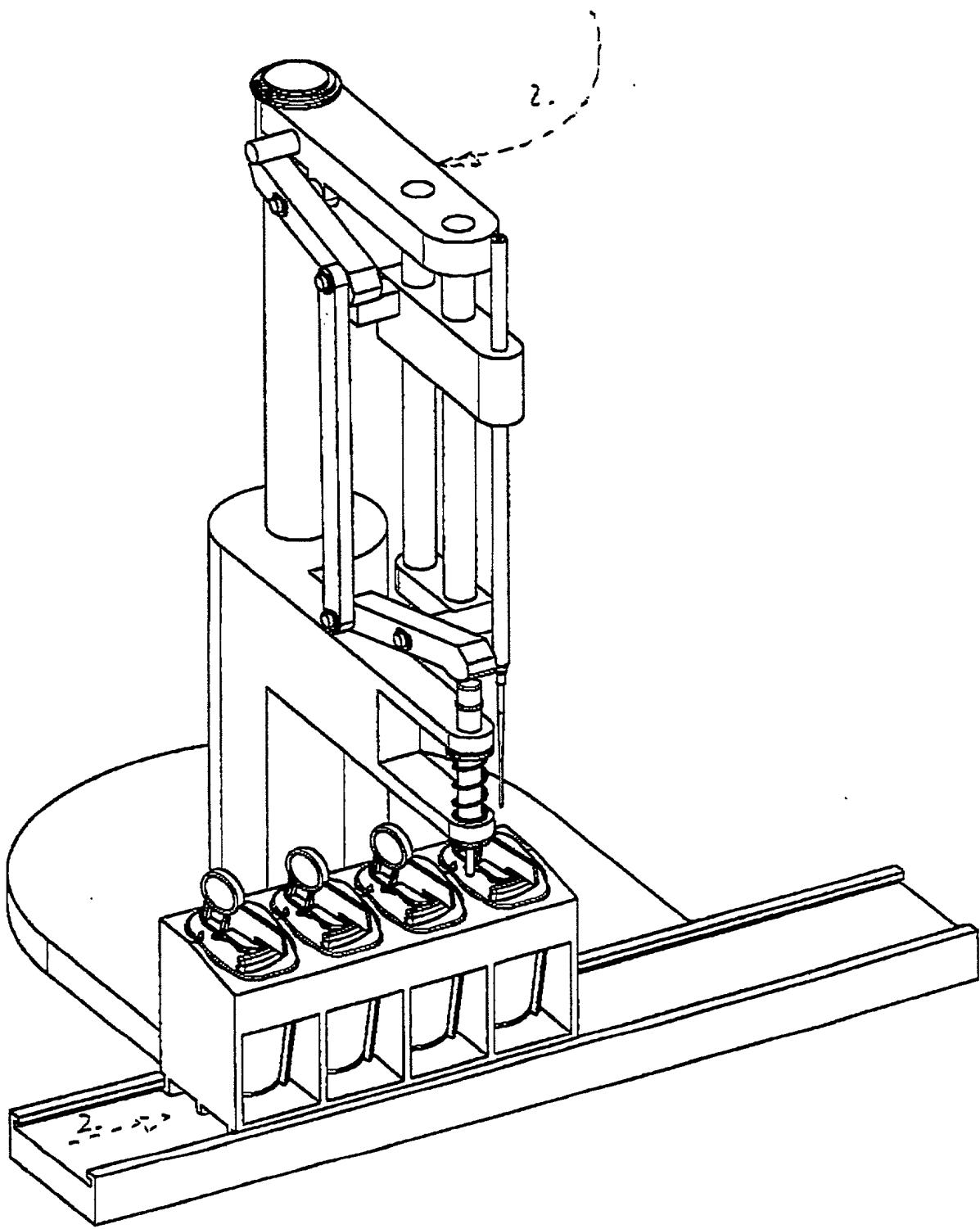


Fig. 3

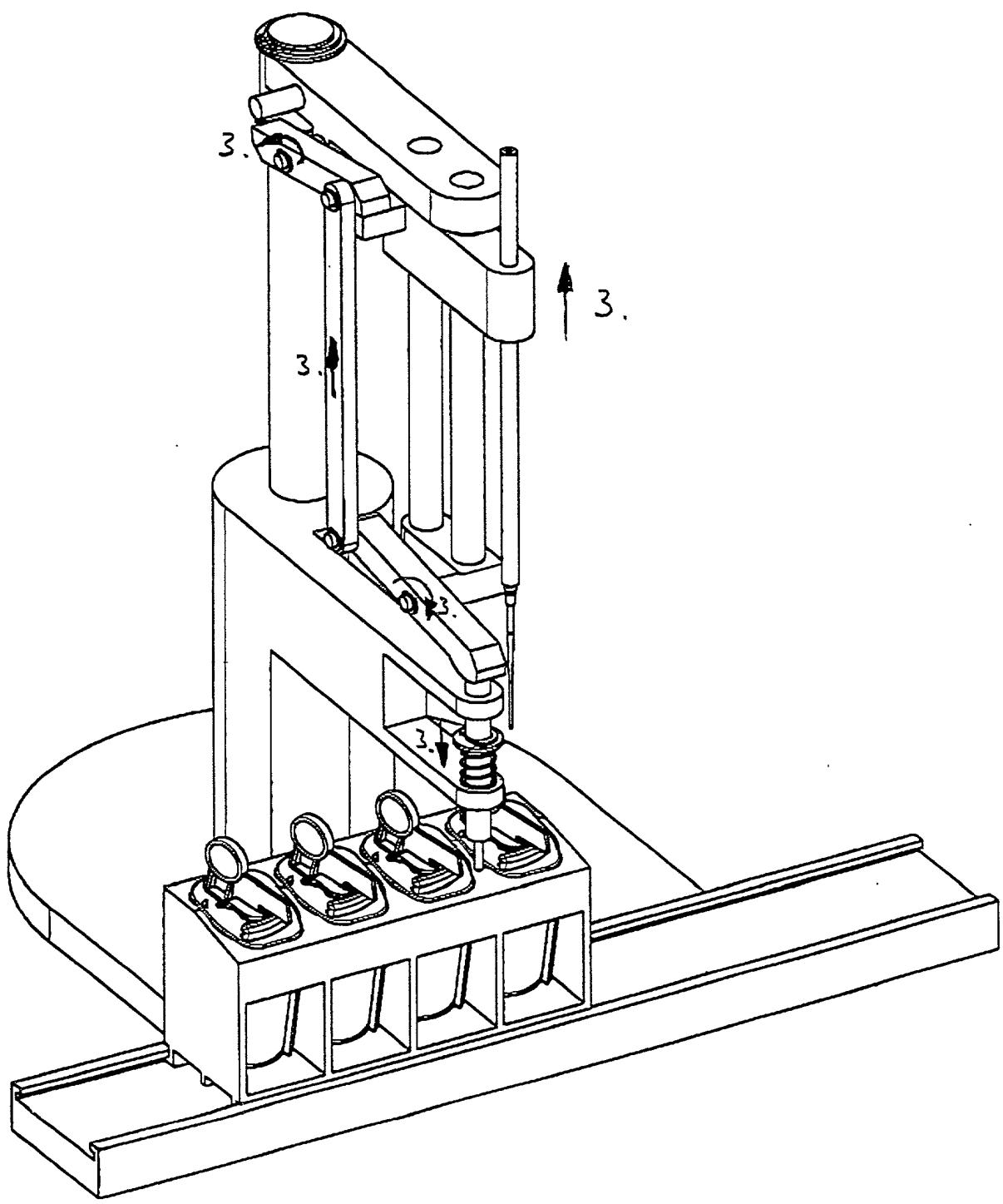


Fig. 4

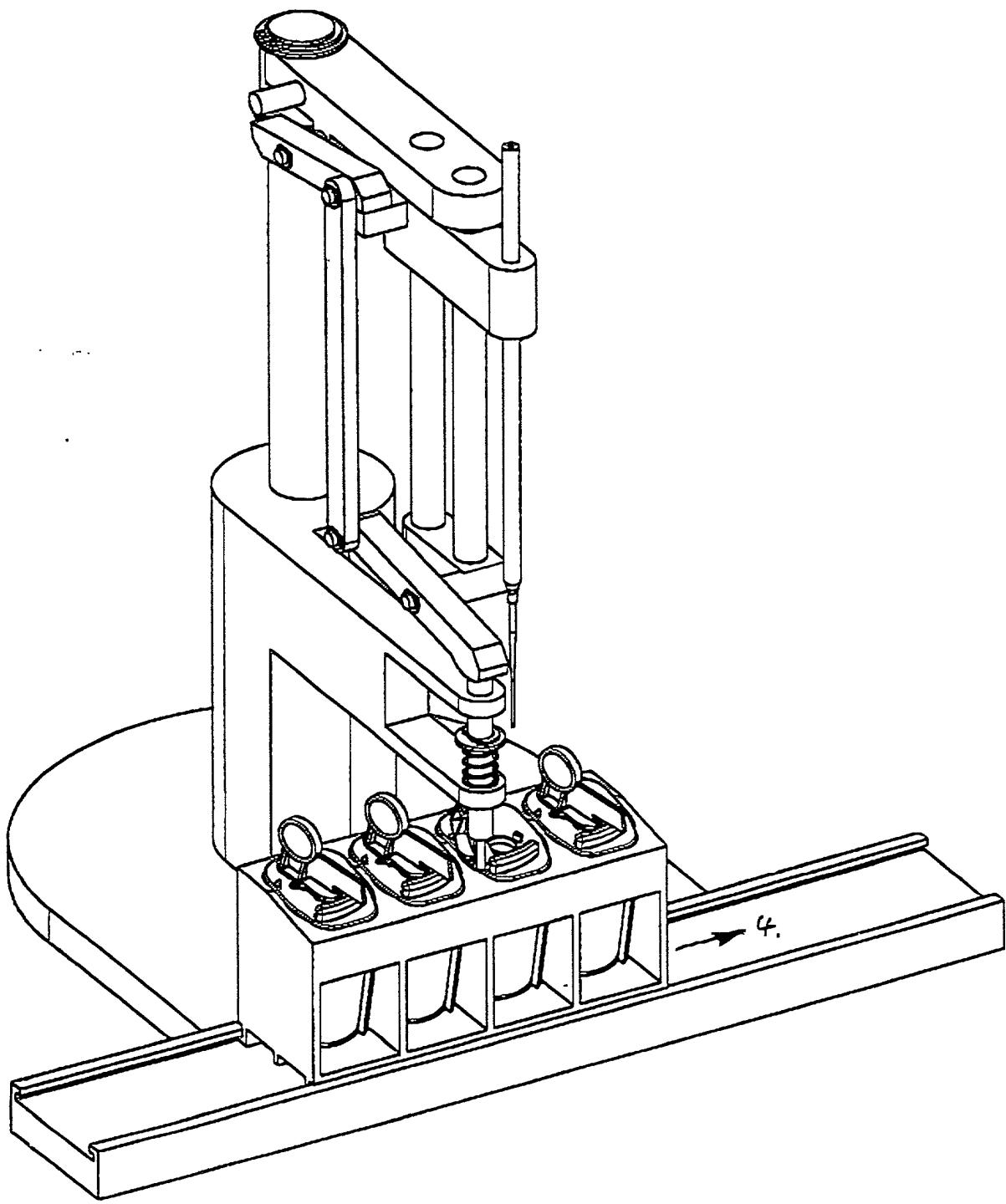


Fig. 5

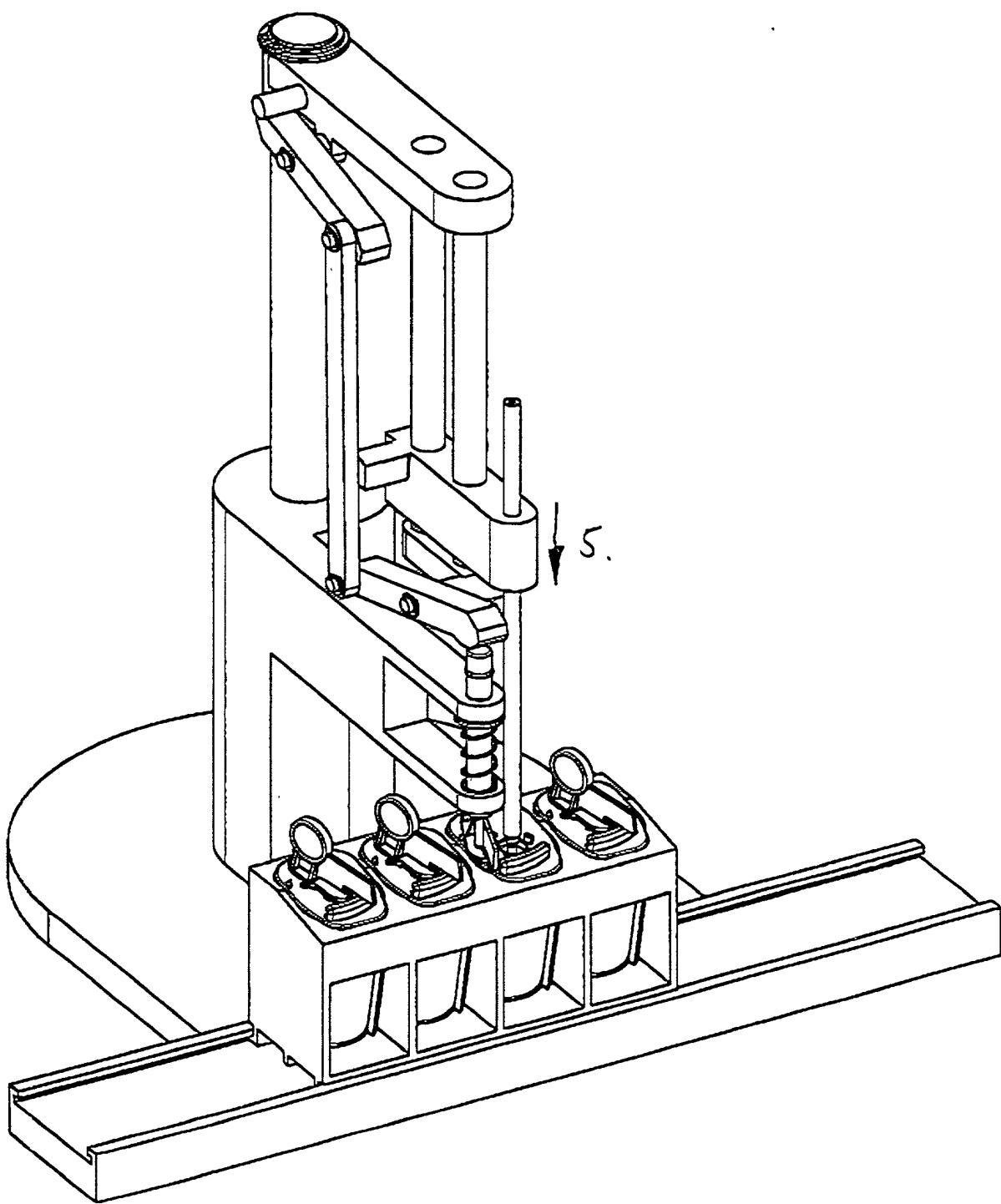


Fig. 6

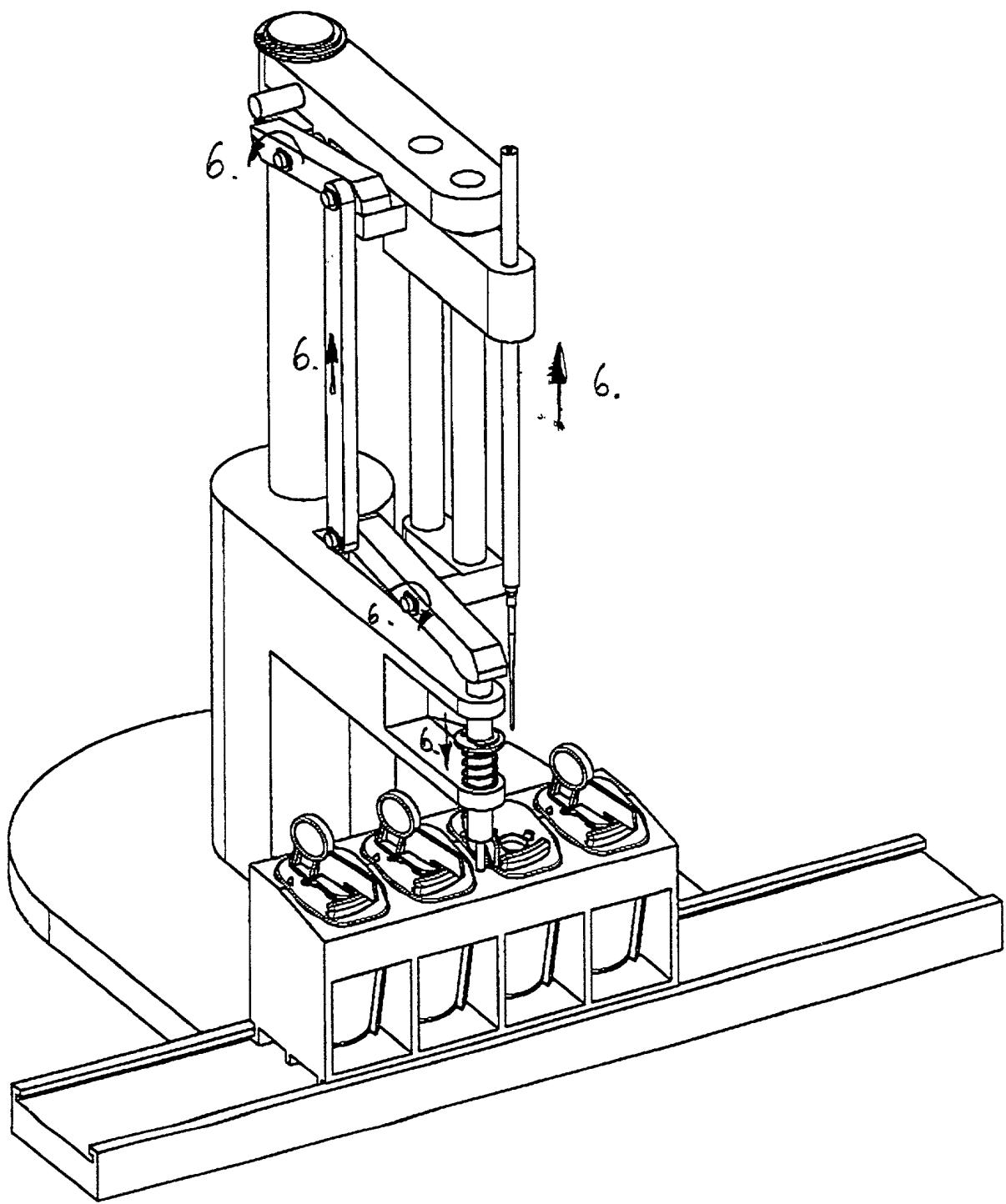
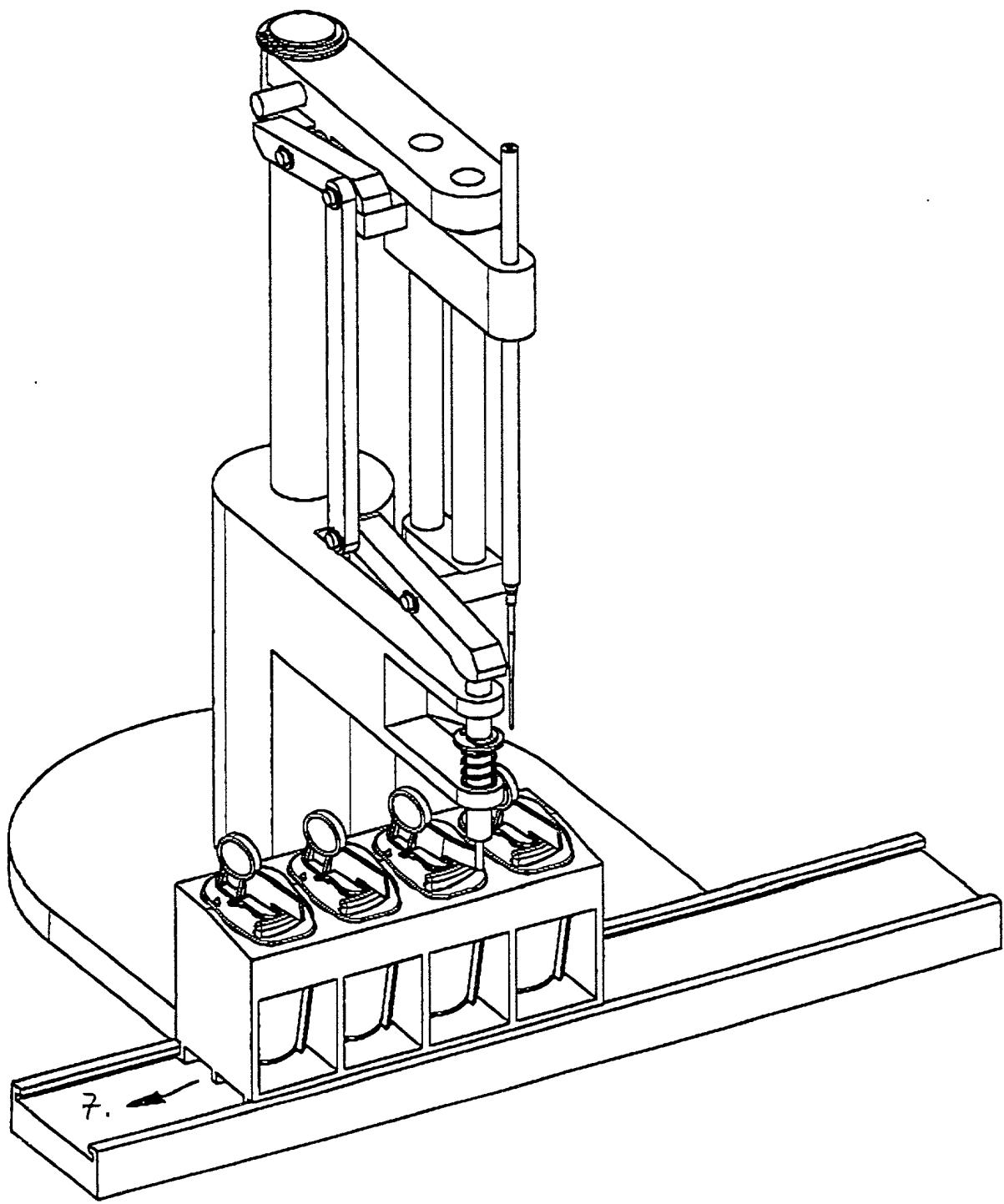


Fig. 7



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Fig. 8

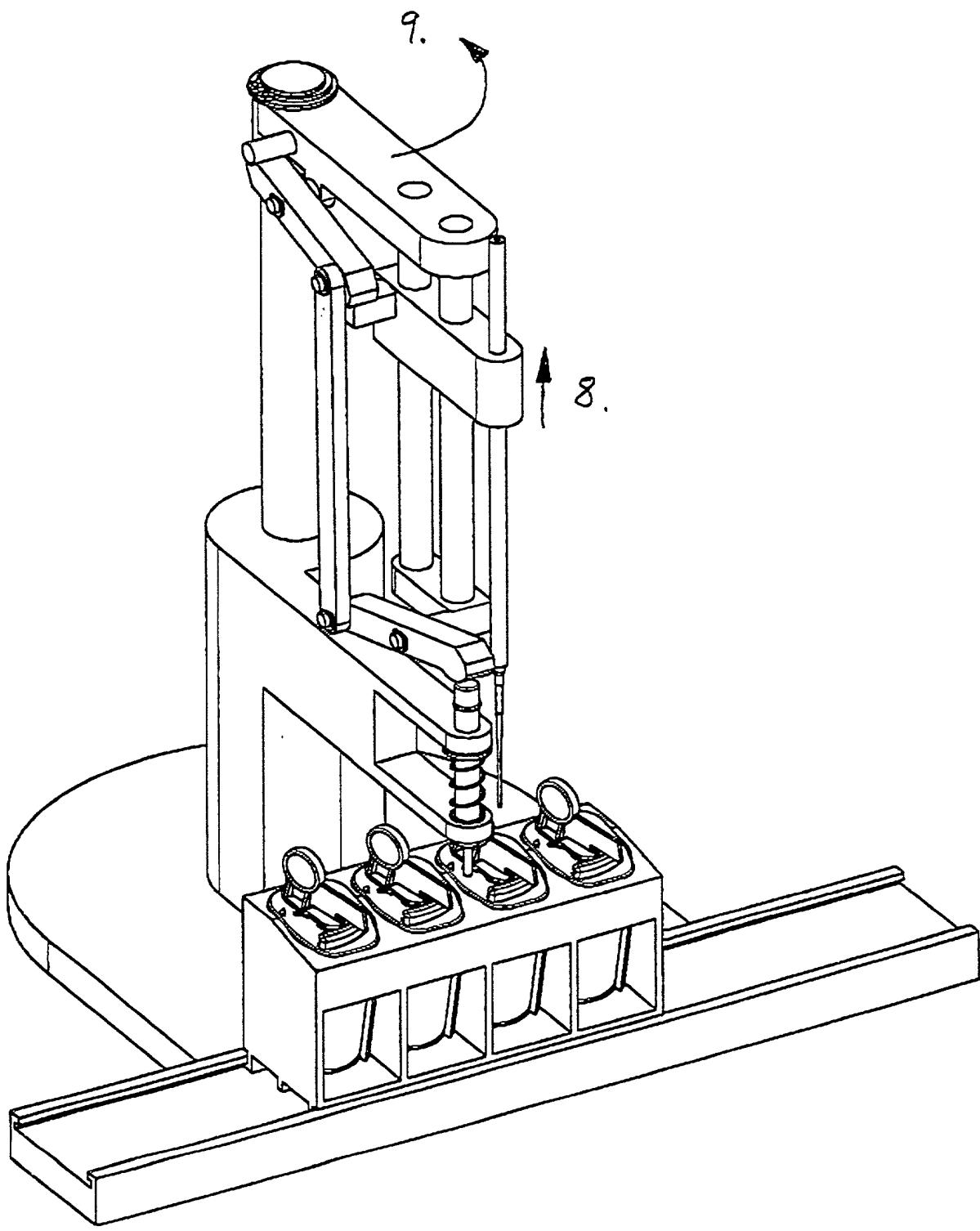


Fig. 9

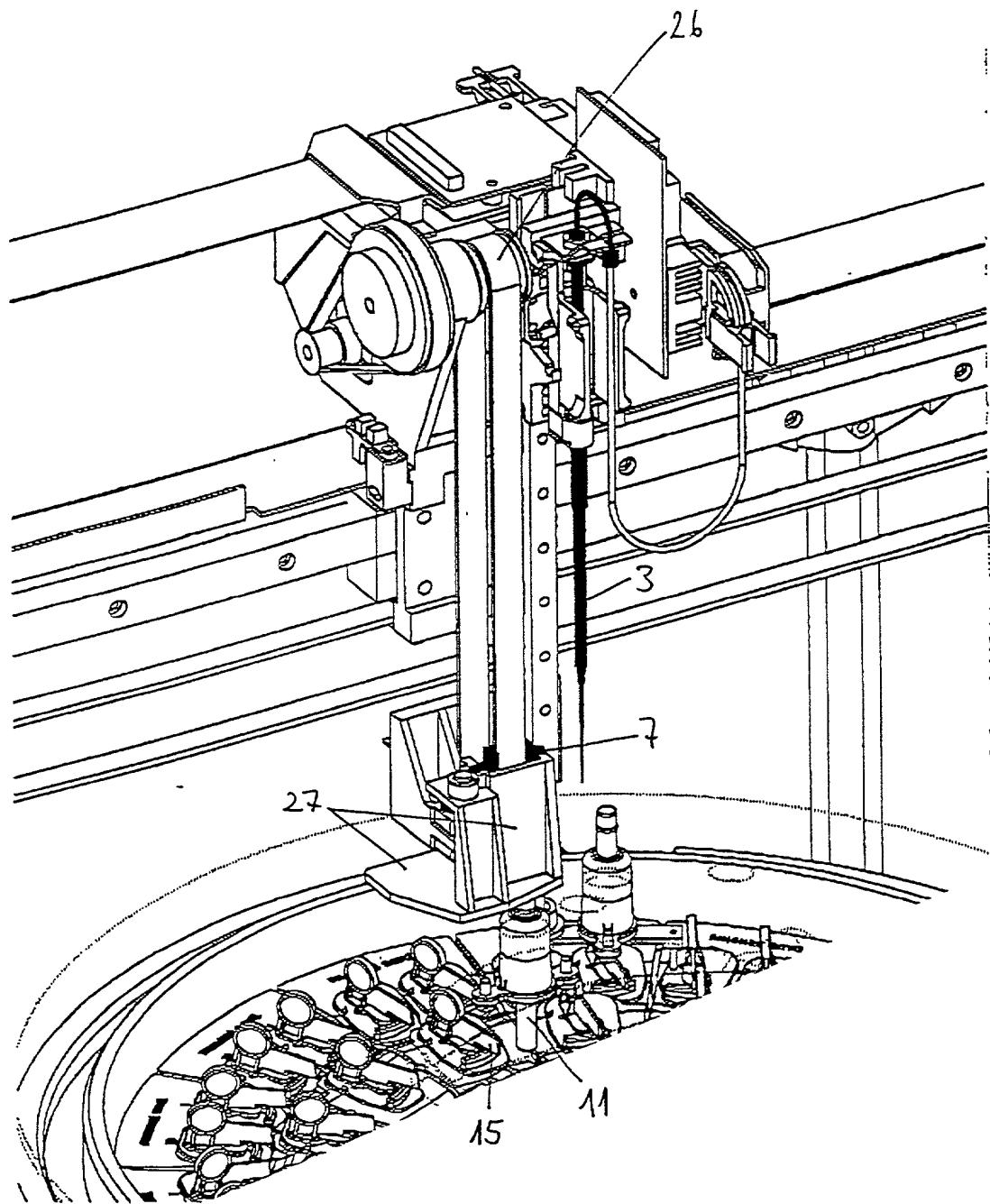


Fig. 10

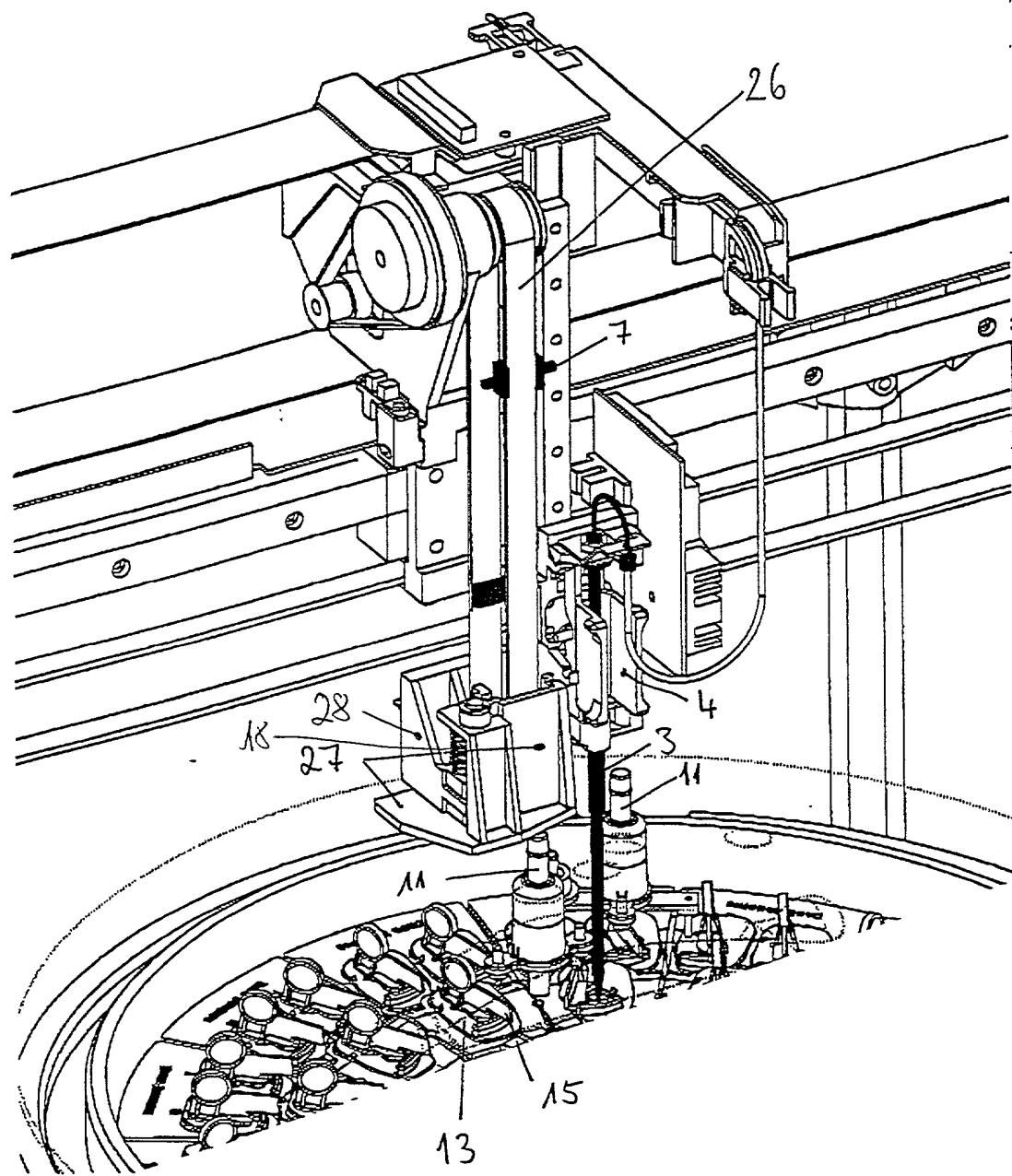


Fig. 11

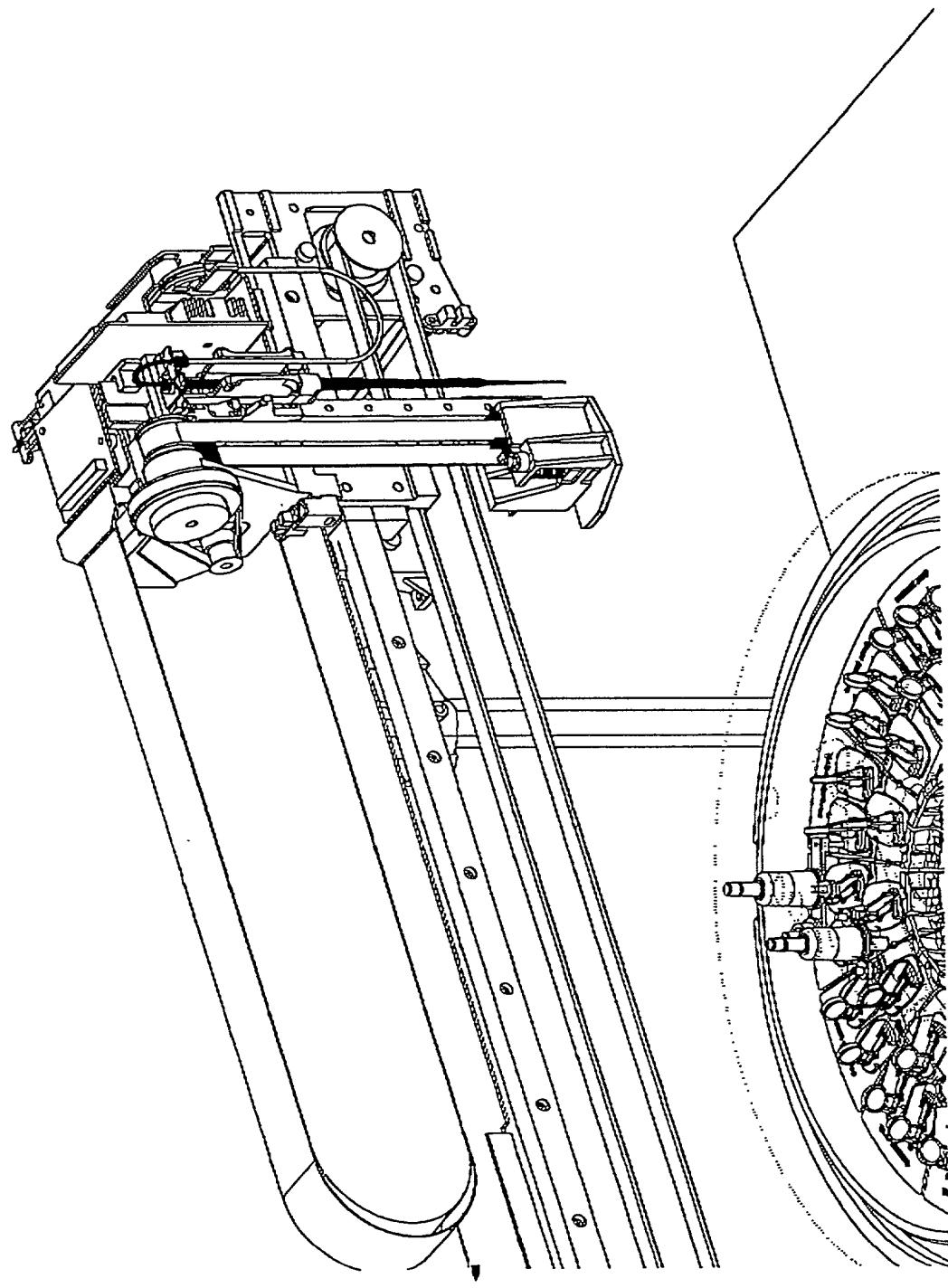


Fig. 12

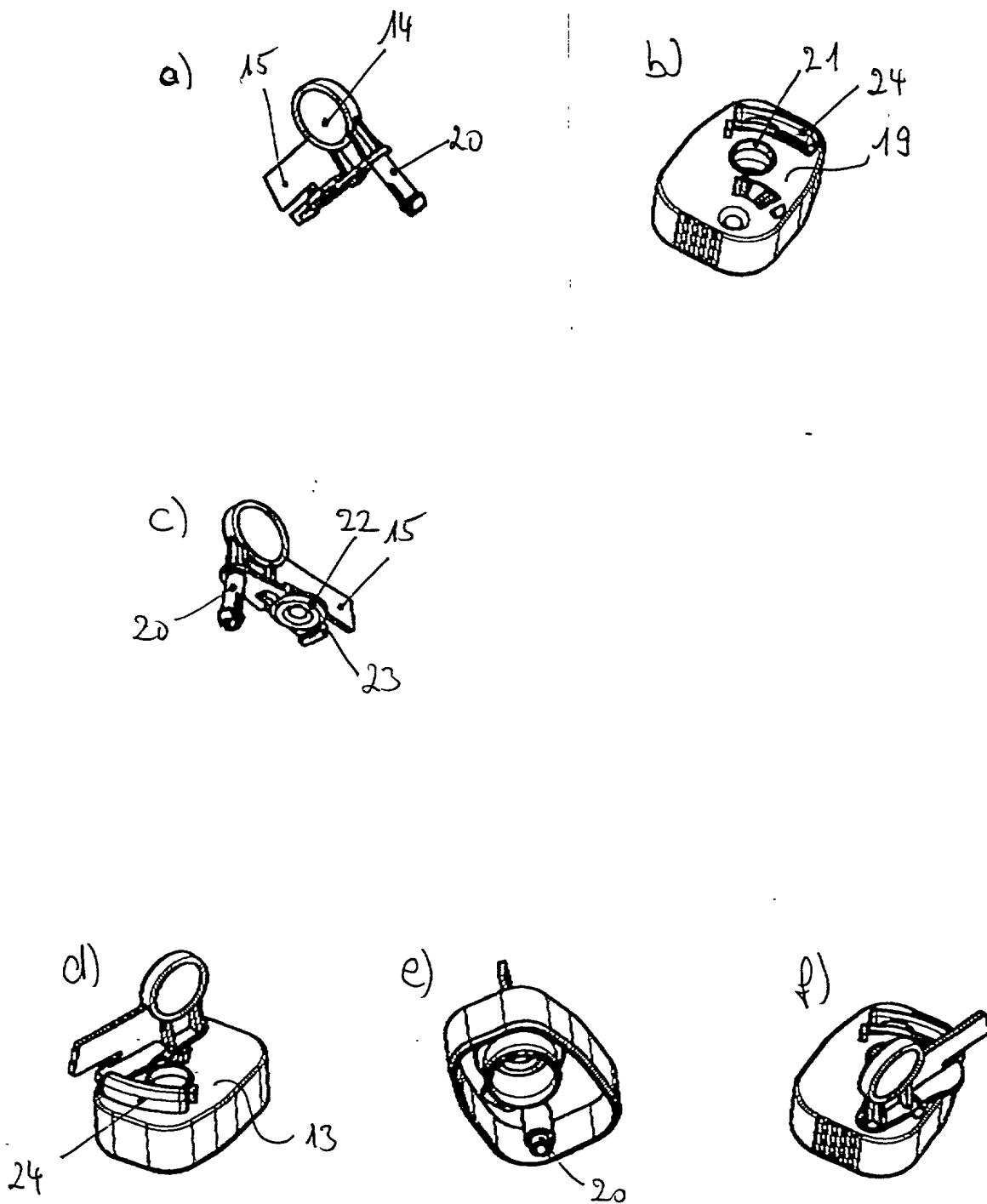


Fig. 13

Section A-A

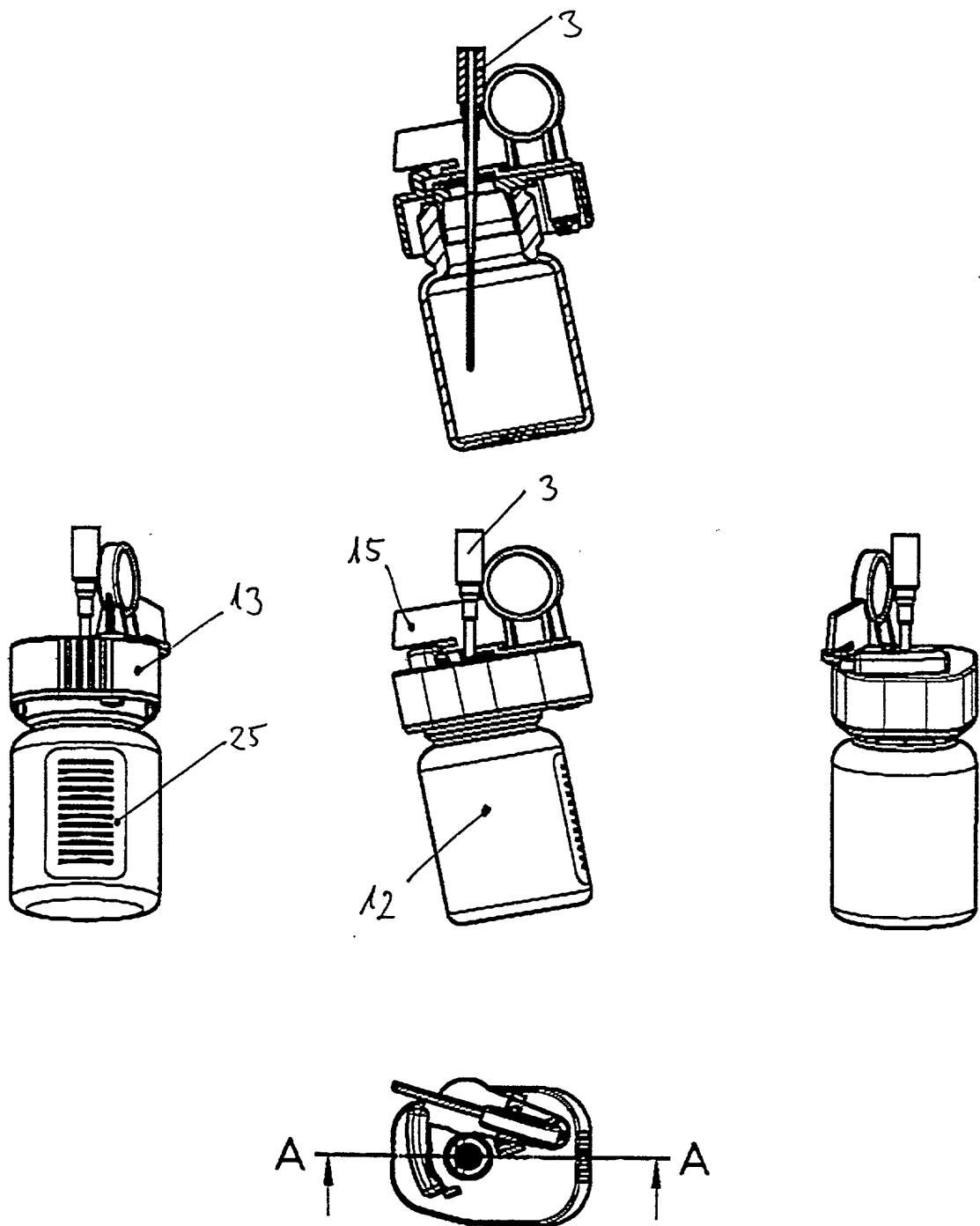
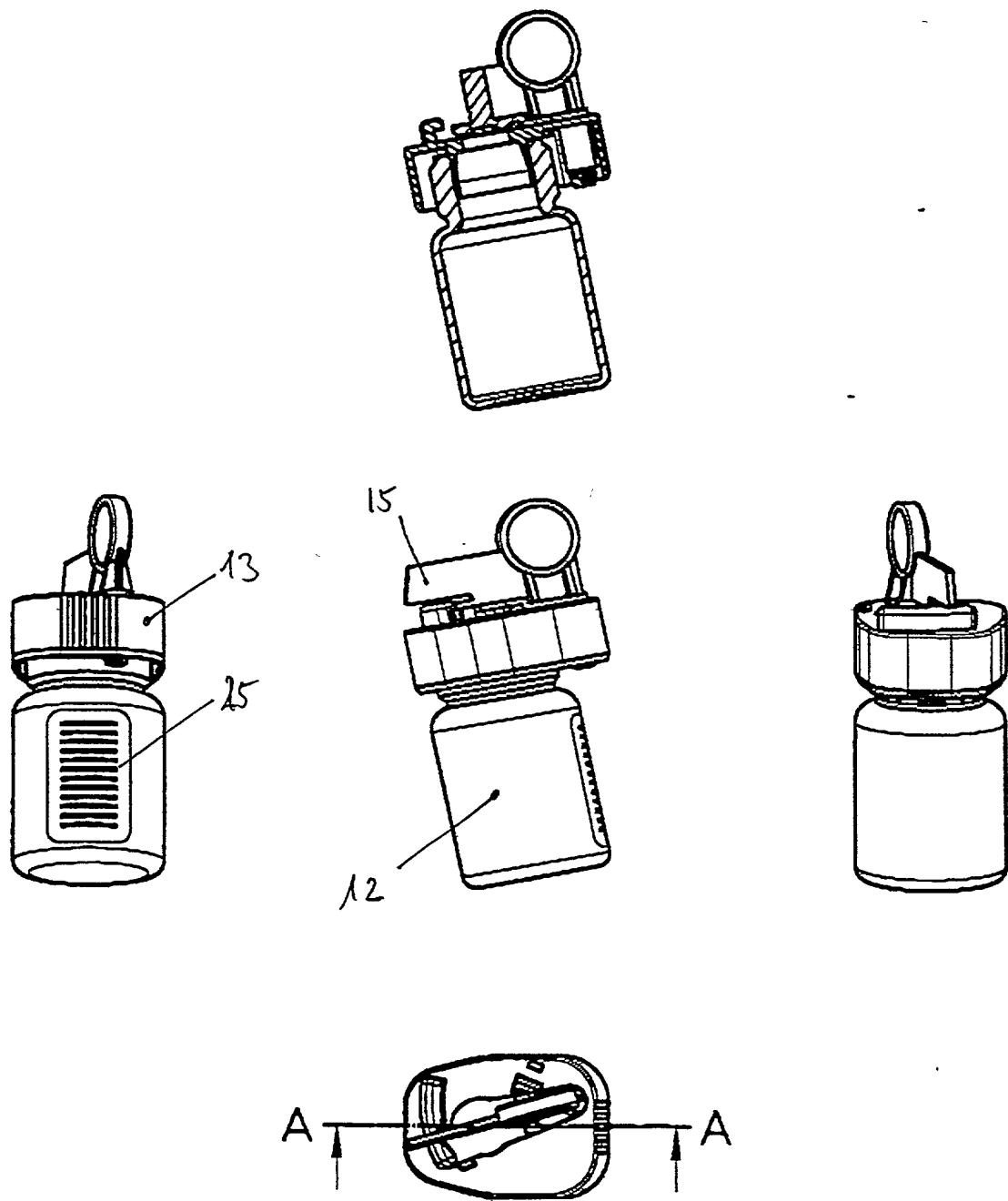


Fig. 14

Section A-A



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PATENT
Attorney Docket No. 5552.1442-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Ralf OTTO et al.)
Serial No.: Not Assigned) Group Art Unit: Unknown
Filed: April 18, 2000) Examiner: Unknown
For: CLOSURE APPLIANCE FOR)
REAGENT CONTAINERS)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

REQUEST FOR APPROVAL OF DRAWING CHANGE

Subject to the approval of the Examiner, it is respectfully requested that Figs. 13 and 14 in the above-captioned application be amended to include the letter sub-headings as indicated in red on the attached copies of the originally filed drawings.

Upon approval of the proposed changes, applicant respectfully requests that the Examiner's requirement for revised formal drawings be deferred until after a Notice of Allowance has issued.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER

By: Elizabeth M. Burke
Elizabeth M. Burke
Reg. No. 38,758

Date: April 18, 2000

LAW OFFICES

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1300 I STREET, N.W.
WASHINGTON, D.C. 20005
202-408-4000

Section A-A

FIG. 13b

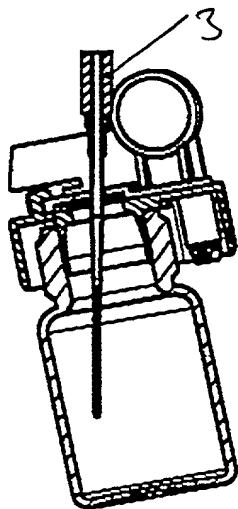


FIG. 13c

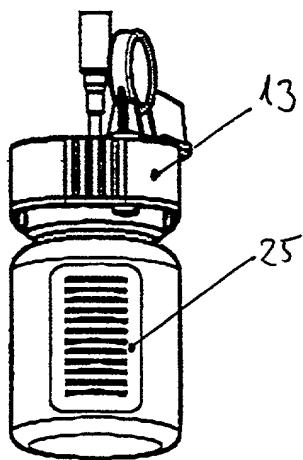


FIG. 13d

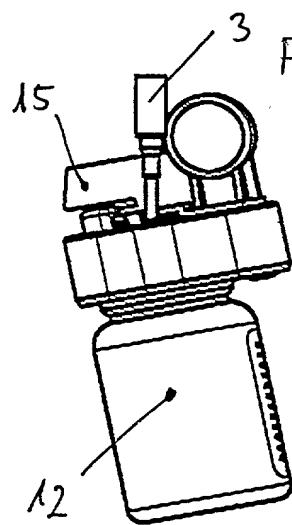


FIG. 13e

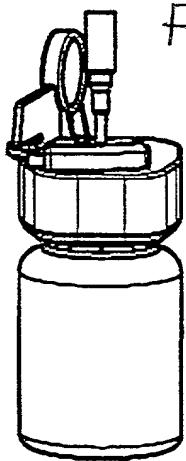
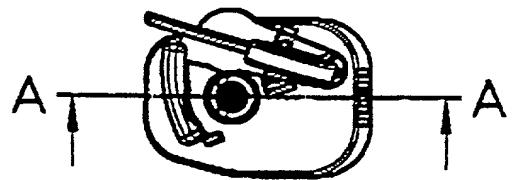


Fig. 13a



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Section A-A

FIG. 14b

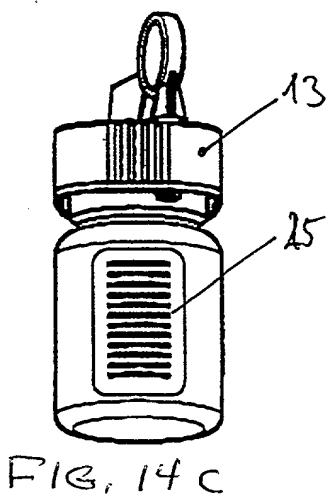
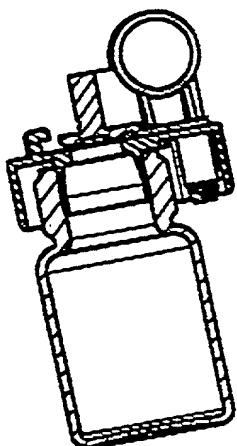


FIG. 14c

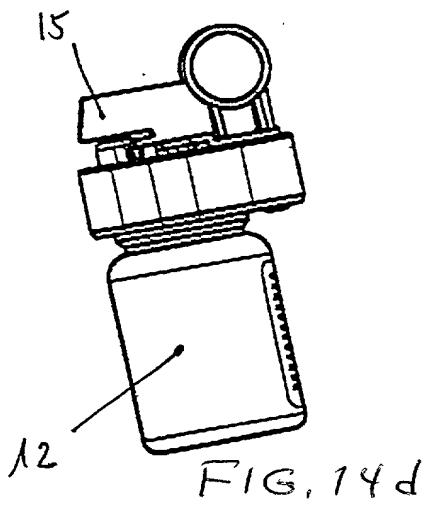


FIG. 14d

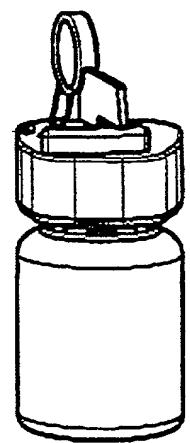


FIG. 14e

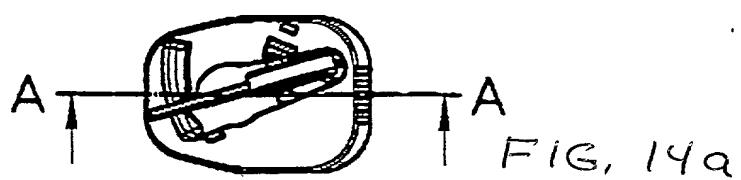


FIG. 14a

DECLARATION FOR PATENT APPLICATION

As below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

"Closure appliance for reagent containers"
(1999/B001 – Ma 1206)

the specification of which is attached hereto / was filed

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I acknowledge the duty to disclose information which is material of the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application in which priority is claimed:

Prior Foreign Application(s) for which Priority is claimed:

Germany 199 17 646.9 of April 19, 1999

And I hereby appoint

Douglas B. Henderson, Reg. No. 20,291; Arthur S. Garrett, Reg. No. 20,338; Jerry D. Voight, Reg. No. 23,020; Herbert H. Mintz, Reg. No. 26,691; Thomas L. Irving, Reg. No. 28,619; Susan H. Griffen, Reg. No. 30,907; Richard B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Carol P. Einaudi, Reg. No. 32,220; Frank E. Caffoe, Reg. No. 18,621; M. Paul Barker, Reg. No. 32,013; Bryan C. Diner, Reg. No. 32,409; Thomas W. Banks, Reg. No. 32,719; Charles E. Van Horn, Reg. No. 40,266; and David S. Forman, Reg. No. 33,694.

all of the firm of FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, Reg. No. 22,540, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therein, and specify that communications about the application are to be directed to the following correspondence address:

FINNEGAN, HENDERSON, FARABOW, GARRETT AND DUNNER

Franklin Square Bldg., Suite 700

1300 I Street, N. W.

Washington, D.C. 20005-3315

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed Marburg, Germany, March 20, 2000

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